FEB 2 6 2002

510(k) SUMMARY
ASCLEPION-MEDITEC AG
Laser System YellowStar K013940

This 510(k) summary of safety and effectiveness for the ASCLEPION-MEDITEC AG Laser System YelowStar is submitted in accordance with the requirements of SDMA 1990 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant: ASCLEPION-MEDITEC AG

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Preparation date: September 2001

Device name: Laser System YellowStar

Common Name: YellowStar

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product code: GEX – Laser instrument, surgical, powered
Panel: 79

Legally marketed: Con Bio CuB-D10

Description: The Laser System YellowStar consists of a laser enclosure, fiber optic delivery system and an computer controlled treatment parameter interface.

Intended Use: The laser system YellowStar intended for treatment of vascular and pigmented lesions.

Comparison to: The specifications of the YellowStar are the same as or very similar to those of legally marketed lasers such as the ConBio CuB-D10 (K932723, K942934) and Metatech Vasculase (K883541, K903883)

Performance data: None. The specifications and intended uses of the laser system YellowStar are the same or very similar to those of claimed predicate devices.
Because of this , performance data were not required.

CONCLUSION: The YellowStar is substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Asclepion-Meditec AG
c/o William Kelley
Asclepion-Meditec, Inc.
2961 West MacArthur Boulevard, #133
Santa Ana, California 92704

Re: K013940
Trade Name: Laser System YellowStar
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: September 1, 2001
Received: November 29, 2001

Dear Mr. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013940

Device Name: *Laser System YellowStar*

Indication For USE Statement:

The YellowStar is intended for treatment of vascular and pigmented lesions.

The laser system YellowStar is restricted to sale to or use by licensed professionals in the United States.

for Mark N Milam

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013940

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)